March 2, 2001

National Human Research Protection Advisory Committee (NHRPAC)
Attn: Dr. Greg Koski
6100 Executive Boulevard, Suite 3B01
MSC-7507
Rockville MD 20892-7507

Dear Dr. Koski:

I am responding to the request for comments on the "draft interim guidance" on "Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subjects Protection."

We concur with the comments sent to you in a joint letter on February 23 from the AAU, COGR, and NASULGC. Specially, we endorse the proposal that the current draft guidance be withdrawn, reconsidered, and then reissued as points for consideration as appropriate by HHS. We also share several of the reservations expressed in the February 23 letter about specific substantive features of the document.

Before listing those reservations, however, we believe it is useful to underscore two larger points that have been largely overlooked in the current national discussion. First, financial conflicts of interest occur in only a very small percentage of clinical studies. Over the last four years, for example, only 60 of the 2,040 (2.9%) clinical studies involving human subjects at the University of Washington involved researchers who had a financial interest of any kind. And even this figure is inflated because the University uses a zero-threshold for disclosure rather than the federal threshold of $10,000. Second, existing federal rules for the protection of human subjects and for the prevention, disclosure, and management of financial conflicts of interest are generally adequate. While this assertion is obviously arguable, it is accurate to say that the current national debate has been created by violations of existing rules (e.g., Gelsinger, Rowsey) rather than by a lack of rules. The challenge is not to create new rules, but rather to find better mechanisms for implementing and enforcing the existing rules.

The question thus becomes whether the "draft interim guidance" makes a positive contribution to management of financial conflicts of interest and the protection of human subjects. We share many of the doubts raised in the joint AAU/COGR/NASULGC letter:

1. The draft guidance is inconsistent with current HHS conflict of interest regulations that recognize both the inevitability of financial involvement and public value of managing them rather than simply eliminating them.

2. The prescriptive character of the draft guidance undermines the process for review and comment established in the Administrative Procedures Act. Prescriptions that will affect literally thousands of researchers and untold number of potential subjects and patients must be developed and reviewed in a more coherent fashion.

3. The draft guidance is ambiguous with regard to the role that should be played by IRBs in the management of financial interest. At one point (Section 1.1) it implies that the burden of review and management can fall to a committee other than the IRB, while at another point (Section 4.3) it lists a large number of financial matter that the IRB "might wish to consider."

4. The discussion of institutional conflicts of interest (1.6) fails to recognize the diversified management of large research institutions. At the University of Washington, for example, equity interests taken in startups are always small and once taken are managed through offices and structures that are completely separate from the research side. In most cases fund managers outside the University make the decisions. These people have no idea what trials are being done. More generally, the overall portfolio of the university is managed by offices and individuals who are either clearly separated from the research process or separated from the University altogether. Institutional conflicts of interest are of concern, but the draft guidance has little to offer.

Events of the last 18 months have created a tremendous amount of local attention and experimentation. At our institution, for example, we have increased reporting requirements, extended the scope of disclosure to include a wider range of technology transfer operations, and expanded the range of information going to the IRBs. In each case, changes were made within the context of local needs and organizational structures. Our changes would not necessarily fit the needs and structure of another institution. The overly detailed and prescriptive lists in the draft guidance are out of tune with the wide variations in local management structures.

As someone actively involved in the development and implementation of institutional policies for the management of conflicts of financial interest, I worry that premature guidance from regulatory agencies will stifle local experimentation and creativity in managing conflicts of financial interest. Moreover, I worry the regulatory environment will come so complex and so frustrating that the public interest will suffer.

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